

**Amendment and Response**

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Applicant(s): Dominic COSGROVE  
Serial No.: 10/698,121  
Filed: 31 October 2003  
For: INDUCIBLE LIGAND FOR  $\alpha$ 1 $\beta$ 1 INTEGRIN AND USES

**Remarks**

The Office Action mailed 30 March 2006 has been received and reviewed. Claims 1-3, 5-8, 10-13, 15, 17, 21, 23, 25, 27, and 28 having been amended, claims 4, 9, 14, 16, 18-20, 22, 24, 26, and 29-42 having been canceled, without prejudice, and claims 43-66 having been added, the pending claims are claims 1-3, 5-8, 10-13, 15, 17, 21, 23, 25, 27, 28, and 43-66. Reconsideration and withdrawal of the rejections are respectfully requested.

Support for the recitation "chronic inflammatory disease associated with the interaction of Collagen XIII with  $\alpha$ 1 $\beta$ 1 integrin positive monocytes" in amended claim 1 can be found, for example, on page 2, line 30, page 9, lines 22-24, and page 10, lines 5-9 of the specification. Support for the recitation "an antibody to Collagen XIII," in amended claims 1, 7, 13, 17, and 23 and new claims 43 and 44 can be found, for example, on page 3, lines 1 and 30-31 and page 11, lines 1-5 and 30 of the specification. Support for the recitation "wherein the antibody reduces the rate of efflux of  $\alpha$ 1 $\beta$ 1 integrin positive monocytes into the interstitial space at the site of inflammation" in amended claim 1 can be found, for example, in original claim 17, page 2, lines 3-7 of the specification, and page 3, lines 5-7 of the specification. Support for the recitation "monoclonal antibody" in amended claims 5, 10, 21, and 24 and new claim 45 is found in original claim 21, page 13, line 29 of the specification, and page 18, line 23 of the specification. Support for new claims 43 and 44 is found, for example, on page 35, line 18, page 38, line 5, and page 41, line 15 of the specification. Support for new claims 46 and 47 is found in original claim 6; support for new claims 48-52 is found in original claims 27 and 28; support for new claims 53-66 is found in original claims 37-40 and in the specification on page 4, lines 22-24, page 13, lines 22-25, page 14, lines 13-16 and page 18, lines 19-23.

**Previously Submitted Information Disclosure Statement**

As noted in the Office Action dated 30 March 2006, the IDS and 1449 documents filed 23 August 2004 and 18 April 2005 have been reviewed. Copies of the Examiner initialed 1449 forms were included with the 30 March 2006 Office Action. However, Applicant is still

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awaiting a reviewed and initialed 1449 form as submitted with the IDS filed 21 October 2004.  
To assist the Examiner, a copy of this 1449 form is enclosed herewith as Exhibit A.

**Objections**

Applicant submits that the Examiner's objection to the specification for containing an embedded hyperlink and/or other form of browser executable code is overcome in view of the amendment of page 16, line 32 of the specification to recite "available on the word wide web at . . ." Withdrawal of this objection to the specification is requested.

Claim 7 has been amended to correct for the inadvertent misspelling of "disrupts."  
Withdrawal of the objection to claim 7 is requested.

**Provisional Double Patenting Rejection**

Claims 1-3, 5-8, 10-13, 15, 17-19, 21-23, and 25 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 25, 34-36, 40, 43-45, and 52 of co-pending Application Serial Number 10/099,573. This rejection is traversed. Applicant respectfully submits that claims 25, 34-36, 40, 43-45, and 52 of co-pending U.S. Patent Application Serial Number 10/099,573 do not teach the administration of an antibody that binds to Collagen XIII. Thus, reconsideration and withdrawal of this rejection under the judicially created doctrine of obviousness-type double patenting is requested.

**The 35 U.S.C. §112, First Paragraph, Rejection**

The Examiner rejected claims 1-3, 5-8, 10-13, 15, 17-19, 21-23, and 25 under 35 U.S.C. §112, first paragraph, that the specification does not enable any person skilled in the art to which it pertains, or which it is most nearly connected to make and use the invention commensurate with the scope of the claims. The Examiner asserted that the specification does not reasonably provide enablement for treating any "**inflammation**" . . . comprising delivering to the tissue any **blocking/active agent** that 'neutralizes the capacity of Collagen XIII to bind to the integrin'" (page 4, Office Action mailed March 29, 2006, (emphasis in original)). Applicant

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respectfully submits that this rejection is moot in view of the various claim amendments. Applicant respectfully submit that the claims, as amended, are not drawn to treating "any inflammation" or administering "any blocking/active agent that neutralizes the capacity of Collagen XIII to bind to the integrin." Reconsideration and withdrawal of this rejection under 35 U.S.C. §112, first paragraph, is requested.

**The 35 U.S.C. §112, Second Paragraph, Rejection**

The Examiner rejected claims 17-20 and 22 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. This rejection is traversed. Specifically, the Examiner asserted that "[c]laims 17 and 22 are incomplete for omitting essential steps." Applicant submits that this rejection is overcome in view of the cancellation of claim 22 and the amendment of claim 17 to recite "[a] method of reducing the rate of monocyte efflux into the interstitial space of chronically inflamed tissues, the method comprising contacting the tissue with an antibody to Collagen XIII wherein the antibody blocks Collagen XIII from binding with  $\alpha$ 1 $\beta$ 1 integrin." Reconsideration and withdrawal of this rejection under 35 U.S.C. §112, second paragraph, is requested.

**The 35 U.S.C. §102(b) Rejection**

The Examiner rejected claims 1-3, 5-8, 10-13, 15, 17-19, 21-23, and 25 under 35 U.S.C. §102(b) as being anticipated by WO 99/61040, as evidenced by the Dominic Cosgrove Declaration filed in Serial Number 10/099,573. This rejection is traversed. As amended, independent claims 1, 7, 13, and 23 (and dependent claims 2, 3, 5, 6, 8, 10-12, 15, 17, 21, and 25) are drawn to methods "comprising administering . . . an antibody to Collagen XIII." Applicant respectfully submits that the teachings of WO 99/61040 are directed to the administration of antibodies that bind to integrins; WO 99/61040 does not teach the administration of an antibody that binds to Collagen XIII. Thus, WO 99/61040 does not

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anticipate the invention of claims 1-3, 5-8, 10-13, 15, 17-19, 21-23, and 25. Reconsideration and withdrawal of this rejection under 35 U.S.C. §102(b) is requested.

**The 35 U.S.C. §102(e) Rejection**

The Examiner rejected claims 1-3, 5-8, 10-13, 15, 17-19, 21-23, and 25 under 35 U.S.C. §102(c) as being anticipated by U.S. Patent No. 6,492,325, as evidenced by the Dominic Cosgrove Declaration filed in U.S. Patent Application Serial Number 10/099,573. This rejection is traversed. As amended, independent claims 1, 7, 13, and 23 (and dependent claims 2, 3, 5, 6, 8, 10-12, 15, 17, 21, and 25) are drawn to methods "comprising administering . . . an antibody to Collagen XIII." Applicant respectfully submits that U.S. Patent No. 6,492,325 does not teach the administration of an antibody that binds to Collagen XIII. Thus, Applicant submit that U.S. Patent No. 6,492,325 does not anticipate the invention of claims 1-3, 5-8, 10-13, 15, 17-19, 21-23, and 25. Reconsideration and withdrawal of this rejection under 35 U.S.C. §102(c) is requested.

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Summary

It is respectfully submitted that the pending claims 1-3, 5-8, 10-13, 15, 17, 21, 23, 25, 27, 28, and 43-66 are in condition for allowance and notification to that effect is respectfully requested. The Examiner is invited to contact Applicant's Representatives, at the below-listed telephone number, if it is believed that prosecution of this application may be assisted thereby.

Respectfully submitted  
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June 30, 2006  
Date

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CERTIFICATE UNDER 37 CFR §1.8:

The undersigned hereby certifies that this paper is being transmitted by facsimile in accordance with 37 CFR §1.6(d) to the Patent and Trademark Office, addressed to: Commissioner for Patents, Mail Stop Amendment, P.O. Box 1450, Alexandria, VA 22313-1450, on this 30<sup>th</sup> day of JUNE, 2006, at 12:55pm (Central Time).

By: [Signature]  
Printed Name: Beth S. McNeely

*[Faint, illegible text]*

<b>INFORMATION DISCLOSURE STATEMENT</b>	Atty. Docket No.: 249.0007 0101	Serial No.: 10/698,121
	Applicant(s): Dominic COSGROVE	Confirmation No.: 8958
	Application Filing Date: 31 October 2003	Group: 1614
	Information Disclosure Statement mailed: 21 October 2004	

## U.S. PATENT DOCUMENTS

Examiner Initial	Document Number	Date	Name	Class	Subclass	Filing Date If Appropriate
	none					

## FOREIGN PATENT DOCUMENTS

Examiner Initial	Document Number	Date	Country	Class	Subclass	Translation	
						Yes	No
	none						

## OTHER DOCUMENTS (Including Authors, Title, Date, Pertinent Papers, etc.)

Examiner Initial	Document Description
	Dennis et al., " $\alpha$ 1 $\beta$ 1 Integrin Facilitates Monocyte Migration into the Tubulointerstitial Space of Fibrotic Kidneys in Murine Model of Alport's Syndrome", Poster Number SU-P0347, American Society of Nephrology (ASN) 35th Annual Meeting & Scientific Exposition. Pennsylvania Convention Center, Philadelphia, PA., November 1-3, 2002.
	Fields et al., "Synthetic Peptides: A User's Guide. Chapter 3: Principles and Practice of Solid-Phase Peptide Synthesis", W.M. Freeman & Company, New York, NY, pp. 77-183 (1992).
	Laakkonen et al., "A tumor-homing peptide with a targeting specificity related to lymphatic vessels", <i>Nature Medicine</i> , 8(7):751-755 (July 2002).
	Lund et al., "In Vivo Modifications of the Maize Mitochondrial Small Heat Stress Protein, HSP22", <i>The Journal of Biological Chemistry</i> , 276(32):29924-29929 (10 August 2001).

EXHIBIT A

EXAMINER	Date Considered
*Examiner: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	